REMARKS

Claim 1-10 had been pending and were examined. Per this amendment, claims 2-25 are pending in this application. Claim 1 has been cancelled without prejudice or disclaimer. Claims 2-10 have been amended, and claims 11-25 have been added.

Claims 2-9 have been amended to correct various grammatical errors and to clarify proper antecedent basis. Claims 2-6 and 10 have also been amended to depend from new claim 11, as claim 1 has been cancelled. Claim 3 has been amended to recite "[t]he transformant according to claim 11; wherein the gene encoding propanol dehydrogenase is a gene encoding 1,3-propanediol oxidoreductase from *Lactobacillus reuteri*." Support for amendments to claim 3 is found in the specification, for example, at least at paragraphs [0101] and [0148] and Figure 2. Claim 10 has been amended to recite "[a] method for producing 1,3-propanediol and/or 3-hydroxypropionic acid comprising: (a) obtaining the transformant according to claim 11, (b) culturing the transformant in the presence of glycerol, and (c) purifying the 1,3-propanediol and/or 3-hydroxypropionic acid." Support for amendments to claim 10 is found in the specification, for example, at least at paragraphs [0177]-[0185]. Thus, the amendments are fully supported by the application as filed. No new matter is added by these amendments.

New claims 11-25 have been added. Below is a table identifying the support for each of the new claims:

New Claim(s)	Exemplary Support from Specification
11	Original claim 1 and paragraphs [0019], [0149], [0158]-[0161]
12	Original claim 10 and Examples 8 and 9
13	Original claim 10 and Examples 8-10
14	Paragraphs [0021]-[0029]
15	Paragraphs [0030]-[0038]
16	Paragraphs [0039]-[0042]

17	Paragraphs [0043]-[0045]
18	Paragraphs [0046]-[0049]
19	Paragraphs [0050]-[0053]
20	Paragraphs [0054]-[0059]
21	Paragraphs [0060]-[0065]
22	Paragraphs [0072]-[0074]
23	Paragraphs [0075]-[0077]
24	Paragraphs [0078]-[0080]
25	Paragraphs [0081]-[0083]

Thus these claims find full support in the specification. Upon entry of the present amendments, claims 2-25 will be pending in this application.

Applicants have also amended the specification at pages 38-39 to remove browser-executable code.

Applicants address below each issue raised in the Office Action of July 9, 2007.

Preliminary Matters

Applicants note with appreciation that the Examiner acknowledged the receipt and equivalence of the Sequence Listing and CRF. Applicants also thank the Examiner for confirming that the Declaration filed September 26, 2006, is in compliance with 37 C.F.R. § 1.63. Applicants further thank the Examiner for considering the IDS submitted May 11, 2005. In addition, Applicants thank the Examiner for confirming the claims for priority. Finally, in response to the Examiner's objection to the specification for containing a hyperlink, Applicants have amended paragraph [0208].

Claim Rejections

I. Rejection of claims 1-7 and 10 under 35 U.S.C. § 112, Second Paragraph

Claims 1-7 and 10 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly "being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." Action at page 3. According to the Examiner, there is "insufficient antecedent basis" for "the" gene and "the" reactivation factor as recited in claim 1. The Examiner also stated that "[i]t is unclear what 'derived from' means" as recited in claims 2-5. The Examiner also rejected claim 6 as reciting a broader range/limitation compared to its parent, claim 1. Finally, the Examiner rejected claim 10 "as being incomplete for omitting essential steps." *Id.* at 5. The Examiner stated that "[t]he omitted steps are: (1) culturing cells, and (2) isolating the 1,3-propanediol and/or 3-hydroxypropionic acid." *Id.*

Applicants respectfully traverse. Nonetheless, to facilitate prosecution and not in acquiescence to the rejection, Applicants have amended the claims to address these comments. Claims 2-5 have been amended to delete the term "derived." Claim 6 has been amended to recite "a gene" as opposed to "the genes." Claim 10 has also been amended to recite steps of carrying out the claimed method. In addition, claim 1 has been cancelled and new claim 11 introduced in its place to provide proper antecedent basis. Finally, all of the claims have been reviewed to ensure proper antecedent basis. Applicants respectfully request the withdrawal of the rejection.

II. Rejection of claims 1-10 under 35 U.S.C. § 112, First Paragraph

Claims 1-10 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner alleged that "[t]he claim(s) contain subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." Action at page 5.

Specifically, the Examiner contends that:

> [T]he disclosure is not sufficient to show that a skilled artisan would recognize that the applicant was in possession of the claimed invention (genus) commensurate to its scope at the time the application was filed. In addition, the disclosure is not sufficient to show that a skilled artisan would recognize that the applicant was in possession of the claimed genus of 'transformants' and 'knockout bacteria' commensurate to its scope at the time the application was filed.

Action at page 9. With respect to claims 1-7, the Examiner states that "any microbe, mold, animal, plant, or insect which has been transformed with a foreign gene is a 'transformant.' The working example of the instant specification only support[s] enzymatic pathway engineering in bacteria, particularly in *E. coli* and *Lactobacillus reuteri*." *Id.* at 6. Similarly, with respect to claims 8-9, the Examiner alleges that "[t]he instant application does not contain support for every knockout bacteria comprising the pdu operon and the gene encoding phosphotransacylase, from which the gene encoding glycerol dehydrogenase is knocked out. In addition, the specification does not contain support for knockout bacteria of the genera *Salmonella, Klebsiella, Listeria, Clostridium, Escherichia, Enterobacter, Caloramator, Acetobacterium, Brucella, Flavobacterium, Fusobecaterium, Citrobacter,* and *Propionibacterium*." *Id.* at 7.

Finally, the Examiner contends that various genes are defined in the specification by hybridization under stringent conditions. *Id.* at 7-8. The Examiner states that:

> With respect to claims limiting a polynucleotide by hybridization conditions, even under relatively high stringent conditions, the claimed nucleotide sequence could hybridize to a genus of polynucleotides that are similar, but not identical to the recited polynucleotides. The limitation by hybridization is obviously generic to a considerable number of nucleotides varying in the length of the nucleic acids, the degree of homologies among the

> sequences, and the biological activities of the promoter, which mayor may not be involved in the function of the genes cite above. This genus also embraces sub-sequences that are unknown and include unsequenced polynucleotides, whose function is yet to be determined.

Id. at 9.

Applicants respectfully traverse. Nonetheless, to facilitate prosecution and not in acquiescence to the rejection, Applicants have cancelled claim 1 and added claim 11. New claim 11 recites "[a] transformant of *E. Coli* or *Lactobacillus reuteri*. . . ." Thus, this amendment overcomes the rejection regarding a transformant of claims 1-7. In addition, Applicants amended claims 8 and 9 to recite "*Lactobacillus reuteri*." Accordingly, this amendment overcomes the rejection regarding the bacteria of claims 8-9. Applicants respectfully request the withdrawal of this rejection.

As to the Examiner's contentions regarding hybridization under stringent conditions, the claims are not drawn to just any gene. Instead, the claims are drawn to genes that encode specific proteins and that exhibit specific protein activities. Moreover, as for the hybridization aspect, the specification makes clear that the level of stringency yields nucleic acids with high homology, 90% or greater. Specifically, the specification provides that:

> Under stringent conditions, a specific hybrid is formed and a nonspecific hybrid is not formed. That is, DNA having high homology (homology of 90% or higher, and preferably 95% or higher) to a given gene hybridizes under such conditions. More specifically, such conditions can be realized by conducting hybridization in the presence of 0.5 to 1 M NaCl at 42°C to 68°C, in the presence of 50% formamide at 42°C, or in an aqueous solution at 65°C to 68°C, and then washing the filter using a 0.1- to 2-fold saline sodium citrate (SSC) solution at a temperature between room temperature and 68°C.

Specification at paragraph [0115]. Thus, the "genus" of genes shares both a function as well as a structure. Those skilled in the art would recognize that the Applicants were in possession of these related genes.

The Examiner directed Applicants to the revised guidelines concerning compliance with the written description requirement. Applicants' disclosure satisfies those guidelines. Specifically, Example 9 of the guideline provides an analysis of a claim reciting an "isolated nucleic acid that specifically hybridizes under highly stringent conditions to the complement of the sequence set forth in SEQ ID NO:1 . . . ." The specification in this Example discloses only a single species - the molecule of SEQ ID NO: 1 - within the scope of the claimed genus. There are no other sequences disclosed in the specification. In analyzing whether the claimed genus satisfies the written description requirement, the guideline recognizes that it does, as follows:

> a person of skill in the art would not expect substantial variation among species encompassed within the scope of the claims because the highly stringent hybridization conditions set forth in the claim yield structurally similar DNAs. Thus, a representative number of species is disclosed, since highly stringent hybridization conditions in combination with the coding function of DNA and the level of skill and knowledge in the art are adequate to determined that applicant was in possession of the claimed invention.

Revised Interim Written Description Guidelines Training Materials, at http://www.uspto.gov/web/menu/written.pdf, pages 36-37. The guideline concludes that "[t]he claimed invention is adequately described," even though only one sequence is disclosed in the specification. *Id.* at p. 37.

Similar to the example in the guidelines, the specification provides nucleotide sequences encoding the genes discussed in the specification, *see e.g.,* Examples 1-6. Thus, a relevant

number of species is disclosed in the instant application. Accordingly, withdrawal of the rejection is respectfully requested.

III. Rejection of Claims 1-7, and 10 under 35 U.S.C. § 112, First Paragraph

Claims 1-7 and 10 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. The Examiner alleged that "[t]he claim(s) contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention." Action at page 10.

Relying on the *Wands* factors, the Examiner states for the "nature of the invention" that "[t]he full scope of the invention encompasses an enormous number of nucleic acids which could hybridize with glycerol dehydratase, propanol dehydrogenase, propionaldehyde dehydrogenase, propionate kinase, and 1,3-propanediol oxidioreductase." Action at page 11. The Examiner also alleges that "[t]he nucleic acids might also encompass very large nucleic acids that hybridize under highly stringent conditions only over a short range near one end of both sequences. In this case, there would be a very low level of homology between the two sequences, despite high stringency hybridization." *Id.* The Examiner further contends that "[t]he limitation by hybridization is obviously generic to . . . the biological activities of the encoded polypeptides, which may or may not be involved in the function of glycerol dehydratase, propanol dehydrogenase, propionaldehyde dehydrogenase, propionate kinase, and 1,3-propanediol oxidioreductase. This genus also embraces sub-sequences that are unknown and include unsequenced polynucleotides, whose function is yet to be determined." *Id.* at pages 11-12.

Applicants respectfully traverse and urge that the Examiner's rejection appears to be based on misapprehension of the invention. Contrary to the Examiner's characterization, while the genus of nucleic acid sequence certainly extends beyond the specific sequences recited in the specification, it is not "enormous." For example, it does not include nucleic acids that "only cover a short range near one end of both sequences" nor does it include polypeptides "which may or may not be involved" in the recited functions. Instead, it includes nucleic acid sequences and polypeptides that have the recited function. As set forth in the specification, "[t]he present invention also includes the use of a gene that hybridizes under stringent conditions with a sequence complementary to DNA comprising part of or the entire DNA comprising the nucleotide sequence as shown in each SEQ ID NO and that encodes a protein having the activity of the reactivation factor for glycerol dehydratase when expressed with another subunit." Specification at paragraph [0112] (emphasis added). Furthermore, the specification provides that "[u]nder stringent conditions, a specific hybrid is formed and a nonspecific hybrid is not formed. That is, DNA having high homology (homology of 90% or higher, and preferably 95% or higher) to a given gene hybridizes under such conditions." Specification at paragraph [0115].

Regarding the state of the art and analysis of the issues, the Examiner alleges that "the quantity of experimentation required to make and/or use the invention, as claimed, is insufficient to enable the invention." *Id.* at 13. The Examiner states that:

> A skilled artisan would not know how to make a nucleic acid which corresponds to the large number of species of nucleic acid encompassed by Claims 1-7. Some of the nucleic acids that fit within the genus of Claims 1-7 would not be homologues of glycerol dehydratase, propanol dehydrogenase, propionaldehyde dehydrogenase, proionate kinase, and 1,3-propanediol oxioreductase. In fact, despite hybridizing under high stringency conditions, these molecules would be structurally and functionally unrelated to the recited genes.

Id. at 12. The Examiner points to Wolcott and Gress to "cast doubt on the homology of the sequences derived through hybridization methods," stating that "[i]f sequences that hybridize under stringent conditions are not homologous or functionally related to those sequences of the genus of claim 16, then there is surely difficulty for the artisan to make and/or use these sequences." *Id.* at 13.

Again, Applicants respectfully traverse.[1] As a preliminary matter, although the Examiner has relied on Wolcott and Gress, these documents have not been provided to the Applicants. Applicants, therefore, have not specifically addressed the alleged teachings of these documents. By not discussing these documents, Applicants in no way acquiesce or submit to the Examiner's contentions.

As set forth above, there is high homology between the sequences that hybridize under stringent conditions, and the encoded proteins have the recognized activity of the recited enzymes. Contrary to the Examiner's position, the claims encompass sequences that are structurally and functionally related. Thus, the skilled person could use routine skill to make the nucleic acid sequences and polypeptides within the scope of the claims. For at least these reasons, the claims are fully enabled, and Applicants respectfully request the withdrawal of the rejection.

IV. Rejection of Claims 1-5 and 10 under 35 U.S.C. § 102(b)

Claims 1-5 and 10 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Dobrogosz et al. (U.S. Patent No. 5,352,586). According to the Examiner, Dobrogosz teaches

[1] Although the Examiner mentioned claim 16, *see* Action at page 13, claim 16 was not pending at the time the Office Action issued.

"*Lactobacillus reuteri* transformants comprising the genes for glycerol dehydratase" and "culturing *Lactobacillus reuteri* transformants in glycerol to produce 1,3-propanediol and/or β-hydroxypropionic acid." Action at pages 14-15.

Applicants respectfully traverse. Solely to facilitate prosecution and not in acquiescence to the rejection, Applicants have cancelled independent claim 1 and added claim 11. New claim 11 recites "[a] transformant of *E. coli* or *Lactobacillus reuteri* comprising genes encoding: large, medium, and small subunits of glycerol dehydratase and/or large, medium, and small subunits of diol dehydratase; large and small subunits of a reactivation factor for glycerol dehydratase and/or large and small subunits of a reactivation factor for diol dehydratase; propionaldehyde dehydrogenase; and propanol dehydrogenase." Accordingly, Applicants refer to claim 11 instead of claim 1 in response to this rejection.

According to the M.P.E.P., "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." M.P.E.P. § 2131 at 2100-67 (citing *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). Dobrogosz does not describe each and every element of the indicated claims.

For example, nowhere does Dobrogosz teach or suggest "transformants" or "recombinant micoorganisms." Dobrogosz teaches "biologically pure strains of *L. reuteri*." Col. 4, lines 3-4. Specifically, Dobrogosz states that Lactobacillus strain 208-A "carries out an anaerobic dehydration (involving glycerol dehydratase) of 2 moles of glycerol yielding 2 moles of β-hydroxypropionaldehyde which in turn is dismutated to 1 mole of β-hydroxypropionic acid and 1 mole of 1,3-propanediol." Dobrogosz at col. 2, lines 61-65. In contrast to Lactobacillus strain 208-A, transformants are not "biologically pure strains" as they are generated using recombinant

biology techniques. According to the instant specification, "[t]ransformants can be obtained by ligating the 4 aforementioned types of genes or parts thereof to an adequate vector and introducing the resulting recombinant vector into a host so as to allow the gene of the present invention to express therein." Specification at paragraph [0120]. Accordingly, Dobrogosz does not disclose "[a] transformant of *E. coli* or *Lactobacillus reuteri* . . . ."

Thus, Dobrogosz does not teach each and every element of claim 11. Since claims 2-5 and 10 depend from claim 11, they include all of the elements of claim 11. Therefore, Dobrogosz does not anticipate any of claims 2-5 or 10-11. Applicants respectfully request the withdrawal of this rejection.

V. Rejection of Claims 1 and 10 under 35 U.S.C. § 102(b)

Claims 1 and 10 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Skraly et al. (U.S. Patent No. 6,329,183). Skraly allegedly teaches "organisms that contain one or both dehydratases typically are able to convert glycerol to 3-hydroxypropionaldehyde to 1,3-propanediol." Action at page 15. Quoting Skraly, the Examiner also stated that "[b]ecause all of the genes necessary to implement the production of poly(3-hydroxypropionate) from central metabolic intermediates via glycerol have been cloned and are available in genetically manipulatable for[m], any combination of plasmid-borne and integrated genes may be used and the implementation of this pathway is therefore not restricted to the scheme outlined herein." *Id.* Further, the Examiner stated that Skraly teaches "transgenic *Escherichia coli* synthesized 1,3-propanediol from glycerol . . . [and] . . . genetically engineered systems for the production . . . of 1,3-propanediol from glycerol." *Id.* at 16.

Applicants respectfully traverse. As set forth above, "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a

single prior art reference." M.P.E.P. § 2131 at 2100-67 (citing *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). Skraly does not disclose "[a] transformant of *E. coli* or *Lactobacillus reuteri* comprising genes encoding: large, medium, and small subunits of glycerol dehydratase and/or large, medium, and small subunits of diol dehydratase; large and small subunits of a reactivation factor for glycerol dehydratase and/or large and small subunits of a reactivation factor for diol dehydratase; propionaldehyde dehydrogenase; and propanol dehydrogenase." as recited in new claim 11. Specifically, Skraly discloses an aldehyde dehydrogenase, not the propionaldehyde dehydrogenase of the instant claims. Moreover, the aldehyde dehydrogenase of Skraly is NAD or NADP-dependent and requires additional steps to produce 3-hydroxypropionyl Co-A, while the propionaldehyde dehydrogenase of the instant claims is Co-A and NAD-dependent and directly produces 3-hydroxypropionyl Co-A. *Compare* Skraly at Example 8 at col. 16, line 64 – col. 18, line 7 with the instant application at Figure 2. Since Skraly does not teach or suggest any aldehyde dehydrogenase that is Co-A and NAD dependent, Skraly does not anticipate the instant claims. For at least this reason, Applicants respectfully request the withdrawal of this rejection.

VI. Rejection of Claims 1-10 under 35 U.S.C. § 103(a)

Claims 1-10 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Skraly et al. (U.S. Patent No. 6,329,183) in view of Dobrogosz et al. (U.S. Patent No. 5,352,586), and as evidenced by Omura et al. (U.S. Publication 2006/0063217). According to the Examiner, "[i]t would have been obvious to the person of ordinary skill in the art at the time the invention was made to culture recombinant bacteria in glycerol to produce 1,3-propanediol and/or 3-hydroxypropionic acid, using a variety of possible enzymatic alternatives in a variety of possible

microorganisms." Action at page 18. The Examiner acknowledged that Skraly "does not teach the source of the genes cited in claims 2-5 as coming from *Lactobacillus reuteri*," and that Dobrogosz "does not particularly teach the knockout limitations of claims 6-9." *Id.* at 17. The Examiner conceded that both references "[d]o not specifically teach the use of the bacteria from the genera *Lactobacillus*, *Salmonella*, *Klebsiella*, *Listeria*, *Clostridium*, *Escherichia*, *Enterobacter*, *Caloramator*, *Acetobacterium*, *Brucella*, *Flavobacterium*, *Fusobacterium*, *Citrobacter*, and *Propionibacterium*, comprising a knock out of the gene encoding glycerol dehydrogenase." *Id.* The Examiner stated, however, that "[t]he person of ordinary skill in the art would have been motivated to make those modifications because 1,3-propanediol and/or 3-hydroxypropionic acid are 'industrially useful as polymers or as starting materials for a range of chemical intermediates' Skraly, abstract." *Id.* at 18. The Examiner also stated that there would be a reasonable expectation of success because "each of these references teach production of 1,3-propanediol and/or β-hydroxypropionic acid from glycerol using microorganisms. Dobrogosz et al. teach culturing Lactobacillus reuteri transformants in glycerol to produce 1,3-propanediol and/or β-hydroxypropionic acid (Col. 12, lines 40-42). Skraly et al. teach 'transgenic *Escherichia coli* synthesized . . . 1,3-propanediol from glycerol' (col. 7, lines 14-15)." *Id.*

Applicants respectfully traverse. As a preliminary matter, Applicants note that the Examiner cited Omura as a basis for the rejection under 35 U.S.C. § 103(a); however, the Examiner has not communicated any rationale for relying Omura. As set forth in the M.P.E.P., "[i]t is important for an examiner to properly communicate the basis for a rejection so that the issues can be identified early and the applicant can be given fair opportunity to reply." M.P.E.P. § 706.02(j). In order to fully respond to the Examiner's comments, Applicants respectfully request that the Examiner provide the rationale for citing Omura in the rejection under § 103(a).

In not responding to Omura here, Applicants in no way agree or acquiesce with the Examiner's rejection.

The Supreme Court recently reaffirmed the framework set forth in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966) for applying the statutory language of 35 U.S.C. § 103:

> Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented." *Id., at 17-18, 86 S. Ct. 684, 15 L. Ed. 2d 545.*

KSR Int'l Co. v. Teleflex Inc., 127 S.Ct. 1727, 1734 (2007), quoting *Graham*, 383 U.S. at 17-18. The Supreme Court further explained that "the factors continue to define the inquiry that controls." *Id.*

The *Graham* test reinforces Applicants' assertion that the claims are not obvious. The scope and content of both Dobrogosz and Skraly are addressed individually in the sections regarding the rejections under 35 U.S.C. § 102(b). Furthermore, the combination of Skraly and Dobrogosz do not teach all of the claimed elements.

The Examiner acknowledged that Skraly and Dobrogosz "[d]o not specifically teach the use of the bacteria from the genera *Lactobacillus* [or] *Escherichia*. . . comprising a knock out of the gene encoding glycerol dehydrogenase." Action at page 17. According to the Federal Circuit, "[t]he mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification." *In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992). Here, the Examiner alleges that the motivation to modify the teachings of Skraly and Dobrogosz is found in Skraly's

acknowledgment that 1,3-propanediol and/or 3-hydroxypropionic acid are "industrially useful as polymers or as starting materials for a range of chemical intermediates." Action at page 18. Despite the fact that 1,3-propanediol and/or 3-hydroxypropionic acid may be industrially important, neither Skraly nor Dobrogosz suggests the desirability of knocking out a gene encoding glycerol dehydrogenase to efficiently produce 1,3-propanediol and/or 3-hydroxypropionic acid.

For at least these reasons, the Examiner has not established a *prima facie* case of obviousness. Applicants, therefore, respectfully request the withdrawal of this rejection.

VI. Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: October 9, 2007

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